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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No. 2327

2:12-md-02327

THIS DOCUMENT RELATES TO:

HON. JOSEPH R. GOODWIN

Tina Harris, et al. v. Ethicon, Inc.., et al No. 2:12-cv-03246

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Motley Rice Law Firm to give medical opinions related to Tina Harris. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae and schedule of previous testimony are attached to this report. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical probability.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these devices. Further, I am familiar with non-mesh options for the treatment of stress urinary incontinence including the pubovaginal sling. I have attending training

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provided by Ethicon, Inc. regarding the TVT device. I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT-O device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Tina Harris:

- Christus Saint Frances Cabrini Hospital;
- The Urology Clinic;
- Delta Pathology Group;
- Alexandria Healthcare for Women;
- Robert Bass, MD

In addition to the review of the medical records listed above, I performed an independent medical examination of Ms. Harris on January 12th, 2017. I have also reviewed additional medical literature, relevant depositions and other TVM related documents (provided in my enclosed reliance list) to assist in formulating my opinions.

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Clinical History

- On November 11th, 2008, Ms Harris presented to Dr. Bass' office with complaints of mixed urinary incontinence (MUI) with a primary component of stress urinary incontinence (SUI). Her past medical history was remarkable for gastroesophageal reflux disease (GERD). She was an active smoker, smoking less than 1 pack per day. She had resorted to wearing pads on occasion. She had no history of dysuria, hematuria, or UTIs. She did have a history of a cystotomy and repair during a C-section in 1997. Physical exam was remarkable for a grade II cystocele, urethral hypermobility, and a post-void residual (PVR) of 106 cc. She was started on Vesicare 10 mg daily.

- On September 2nd 2009, Ms. Harris presented to Dr. Bass with complaints of ongoing MUI with a primary stress component. She had been given Vesicare to help her urgency symptoms which had helped but caused significant constipation necessitating cessation. She expressed an interest in sling surgery and Dr. Bass recommended that she undergo this procedure at the time of planned robotic hysterectomy/bilateral salpingo-oophorectomy.

- On September 25th, 2009, Dr. Bass performed a TVT-O procedure uneventfully. He memorialized placement of the sling in a tension-free fashion using a #11 Hagar dilator as a spacer. Cystoscopy revealed no injury to the bladder. She was discharged home on September 27th after an uneventful recovery from her sling and robotic hysterectomy/ bilateral salpingo-oophorectomy procedure.

- On October 13th, 2009, Ms. Harris saw Dr. Bass for a post-operative check. She was continent and had occasional leg pain.

Methodology

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My general opinions based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT-O, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

It is my opinion the IFU for the TVT-O in 2009 was not sufficient to enable informed consent from the patient. The TVT-O IFU provided:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.

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- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT-O mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina and peri-vaginal tissues persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

The TVT-O IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event. These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. These events were reported in the mid-urethral sling literature prior to when Ms. Harris was implanted. In my opinion, a patient considering a mid-urethral

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sling cannot be properly consented without discussing these potential adverse events.

General Opinion No. 2

Safer alternatives designs and procedures existed in 2009 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy.

In 2009, alternative successful and safer sling procedures were available, including biologic slings or autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Ms. Harris was unable to receive proper informed consent relating to such safer alternatives because of the lack of information in the TVT-O IFU inherent to the risks of using synthetic mesh as an alternative to autologous fascia. As such, Dr. Bass was unable to warn Ms. Harris of the subsequent complications she has suffered from.

Case Specific Opinion No. 1

Ms. Harris suffered vaginal sling contraction and scar plate formation as a result of the physical properties of the TVT-O device. These conditions are documented in my IME.

A. Contraction/Shrinkage

Ms. Harris' TVT-O contracted post implantation. My physical exam demonstrated tenting of the mesh especially at the left vaginal sulcus consistent with contraction

I have observed "tented" pieces of transvaginal mesh in my clinical practice that are the result of post-implantation contraction or shrinkage of the mesh.

B. Scar Plate

During my physical examination of Ms. Harris, I identified palpable induration beneath her sling at the vaginal sulci consistent with scar plate formation.

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I have observed scar plate formation in patients such as Ms. Harris who have had TVT-O slings implanted.

Case Specific Opinion No. 3

Ms. Harris' vaginal pain and dyspareunia was caused by contraction of the TVT-O device, and scar plate formation. Recognized causes of dyspareunia following synthetic sling surgery include: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5) infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury (7) lichen sclerosis; (8) vaginal tissue atrophy; and (9) pelvic floor dysfunction.

I am able to rule in contraction and scarring as potential causes of Ms. Harris' vaginal pain and dyspareunia. These conditions are documented in my IME of Ms. Harris as previously stated above. Further, palpation of anterior vaginal wall in the area of the sling particularly in the left vaginal sulcus produced pain in Ms. Harris.

Pain produced on palpation on exam enables me to rule in contraction and scarring as potential causes of Ms. Harris' dyspareunia.

I am able to exclude infection, inflammation, neuromuscular injury, paraurethral banding, lichen sclerosis, and pelvic floor dysfunction as causes of Ms. Harris' dyspareunia and vaginal pain because I have seen none of these findings documented in the medical records nor were they detected on physical exam.

Vaginal tissue atrophy is excludable as the cause of Ms. Harris' dyspareunia as she never was diagnosed with this condition. Although she did undergo bilateral oophorectomy in 2009, my IME revealed no evidence of vaginal tissue atrophy. Moreover, my pelvic exam at that time revealed tenderness in the area of the left groin where she complained of site-specific dyspareunia.

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Case Specific Opinion No. 4

Ms. Harris continues to have dyspareunia presently. As part of my expert review and preparation of my opinion regarding Ms. Harris, I performed an independent medical exam of this patient on January 12th, 2017. At that time, the patient reported several bothersome symptoms including voiding dysfunction, pelvic pain, and dyspareunia. Her voiding dysfunction consisted of urinary incontinence, primarily urgency urinary incontinence as well as a slow stream and incomplete emptying. With regards to her pelvic pain, she described left groin and left leg pain that started several weeks after her surgery and have never resolved.

Additional significant findings include indurated tissue in the area of her sling in the bilateral sulci of the vaginal canal, left greater than right. As part of the foreign body reaction to synthetic mesh, the periurethral, perivesical, and vaginal tissues create dense fibrotic scar tissue which compromises the elasticity and compliance of these tissues. As such, when patients present with complications from synthetic mesh slings, they tend to develop a combination of voiding dysfunction, sometimes manifest as obstructive in nature, in addition to urinary incontinence that is often both stress incontinence in combination with urgency urinary incontinence. This relates to a combination of factors, one being the development of non-compliant "pipestem" urethral tissues that are unable to coapt and therefore hold urine; the second factor relates to a combination of (1) inflammation rendering the bladder muscle (or detrusor muscle) unstable, as well as (2) scarring of the bladder muscle adjacent to the synthetic mesh foreign body response, in which the bladder muscle's ability to contract is compromised because of scarring and fibrosis.

Case Specific Opinion No. 5

Ms. Harris' future prognosis as it relates to her pelvic pain, dyspareunia, and voiding dysfunction is guarded. Because she has pelvic mesh still inside of her body, she will continue to suffer from pelvic pain and dyspareunia. Moreover, she has pelvic tenderness and scar plate formation in the vaginal sulci where her sling is located. Even if she were to have all of her mesh removed, the surgery require to execute this procedure is extensive, complicated, and almost exclusively performed in tertiary academic centers. I anticipate that if heroic surgery were performed to

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remove all of her mesh that she would develop further scarring and fibrosis inherent to this procedure.

In as much an autologous fascial sling or other procedures (not involving synthetic mesh) for incontinence might be considered if her mesh were to be removed, these would be inappropriate at the current time because of the fact that she still has a mesh sling present. Autologous fascial slings placed in the setting of scar tissue, a likely finding should she have her sling removed, would have a lower success rate and a higher complication rate than if it were performed in the absence of scarring. For this reason, Ms. Harris is not an ideal candidate for this type of surgery and is best treated with medical therapy in combination with lifestyle modifications and pelvic floor physiotherapy. Although these interventions should be somewhat helpful, they most certainly will not resolve the voiding dysfunction she currently suffers from.

With regards to her dyspareunia, her symptoms might be ameliorated with sling removal. Once again, this would be a heroic procedure performed in a tertiary academic center and would likely create further fibrosis and scarring which would more likely than not result in persistent dyspareunia. In summary, within a reasonable degree of medical certainty, the voiding dysfunction, pelvic pain, and dyspareunia Ms. Harris currently suffers from will be a lifelong condition for this patient. Moreover, alternative successful and safer sling procedures were available at the time of her original synthetic mesh sling implantation, including the use of a biologic sling or autologous fascial sling with suture. These safer alternative sling procedures would not have resulted in the same symptoms and injuries that Ms. Harris now suffers.

These represent my current opinions in this case. As any additional material becomes available, I reserve the right to modify or add to this opinion.

Sincerely,

Konstantin Walmsley, M.D.
12/17/17

History and Physical

Patient Name:	Tina Harris	**Visit Date:**	January 12, 2017
Patient ID:	859630	**Provider:**	Konstantin Walmsley, MD
Sex:	Female	**Location:**	NJU-P24 (Glen Ridge)
Birthdate:	December 30, 1966	**Location Address:**	777 Bloomfield Avenue Glen Ridge, NJ 070282325
Referring Provider:	Dr. Konstantin Walmsley MD	**Location Phone:**	(973) 429-0462

Chief Complaint

- IME Patient

History Of Present Illness

Dx'd with cystocele and MUI, primarily SUI in 2008.
G2P2, one C-section; 2 boys 29, 31.
Hx remarkable for C-section and cystostomy repair in the 1987.
In 2009, she had a complete vaginal hysterectomy/oophorectomy by Dr. Bieber.
Had a mesh sling placed.
Developed left groin/leg pain after about 2-4 weeks.
Told by Dr. Bass it might be related to scarring.
Her incontinence got about 40 % better on Vesicare; this caused constipation/dry mouth.
Still sexually active, last in November but finds it painful and somewhat embarrassing because of her incontinence.
Describes pain as in the "bladder" area and left groin.
Now her incontinence is the same, but more UUI than SUI.
Currently uses 2-3 pads/day, damp to wet when changed.
No more constipation.
Has had a few UTIs since her surgery.
Stream is slow and she feels like she can't empty well.

Past Medical History

Disease Name	Date Onset	Notes
Anxiety disorder	--	--
Bladder infection	--	--
Blood in urine	--	--
Depression	--	--
High cholesterol	--	--
Hypertension	--	--
Incontinence	--	--

Medication List

Name	Date Started	Instructions
metoprolol succinate oral		--

Allergy List

Allergen Name	Date	Reaction	Notes
doxycycline	--	--	--
Latex	--	--	--

Social History

Finding	Status	Start/ Stop	Quantity	Notes
Alcohol	Light	--/--	--	--
Caffeine	Heavy	--/--	--	--

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Denies illicit substance abuse	--	--/--	--	--
Tobacco	Current every day	--/--	--	--

Review of Systems

Constitutional
- **Denies** : fever, chills

Eyes
- **Denies** : changes in vision, double vision

HENT
- **Denies** : sore throat, headaches

Cardiovascular
- **Denies** : chest pain, irregular heart beats, dyspnea on exertion

Respiratory
- **Denies** : shortness of breath, sleep apnea

Gastrointestinal
- **Denies** : nausea, vomiting

Genitourinary
- * See HPI

Integument
- **Denies** : rash, itching

Neurologic
- **Denies** : tingling or numbness, seizures

Musculoskeletal
- **Denies** : back pain, muscular weakness

Endocrine
- **Denies** : cold intolerance, heat intolerance, weight gain, weight loss

Psychiatric
- **Denies** : anxiety, depression

Heme-Lymph
- **Denies** : easy bleeding, lymph node enlargement or tenderness

Allergic-Immunologic
- **Denies** : frequent illnesses

Vitals

Date	Time	BP	Position	Site	L\R	Cuff Size	HR	RR	TEMP(°F)	WT	HT	BMI kg/m^2	BSA m^2	O2 Sat	HC
01/12/2017	01:27 PM	121/83	Sitting				74 - R								
01/12/2017	01:17 PM									229lbs 0oz	5' 3"	40.57	2.15		

Physical Examination

Constitutional
- **Appearance** : well nourished, *large body habitus*, ambulates without difficulty, in no acute distress
- **Ability to Communicate** : Normal communication ability

Eyes
- **Conjunctiva and Eyelids** : Conjunctiva and eyelids appear normal
- **Sclera** : White without injection

Neck
- **Thyroid** : gland size normal, nontender, no nodules or masses present on palpation, gland position midline, trachea midline

Chest
- **Respiratory Effort** : breathing unlabored, no accessory muscle use
- **Auscultation** : normal breath sounds

Cardiovascular
- **Heart** :

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- **Auscultation** : Heart rate is regular with normal rhythm. No murmurs are heard.

- **Peripheral Vascular System** :
  - **Peripheral Circulation** : No evidence of edema, cyanosis or distal hair loss present. No purpura present. Normal capillary refill. No varicosities are present.

Gastrointestinal

- **Abdominal Exam** : tone normal without rigidity or guarding, no CVA or abdominal tenderness, normal bowel sounds, no masses present, non-distended
- **Hernias** : No evidence of a right inguinal hernia, No evidence of a left inguinal hernia, no incisional hernias present, normal appearing umbilicus

Genitourinary

- **External Genitalia** : normal appearance for age
- **Vagina** : color normal, moderate tenderness underneath the urethra, especially at the sulci left greater than right. Mild amounts of indurated tissue noted at the sulci, left greater than right with some tenting of the sling especially on the left.
- **Urethra** :
  - **Urethral Meatus** : Meatus is within normal limits
  - **Urethral Body** : urethra palpation normal, urethra structural support normal, no hypermobility present, no leakage present
- **Bladder** : non-tender to palpation, small cystocele present, no bladder distension present
- **Cervix** : absent
- **Uterus** : absent
- **Perineum** : perineum normal, perineum intact, no perineal rashes or skin lesions present

Lymphatic

- **Neck** : no neck lymphadenopathy present
- **Groin** : no groin lymphadenopathy present

Musculoskeletal

- **Right Lower Extremity** : no tenderness to palpation, no edema present, no ecchymosis present
- **Left Lower Extremity** : no tenderness to palpation, no edema present, no ecchymosis present

Neurologic and Psychiatric

- **Orientation** : oriented to person, place and time
- **Mood and Affect** : normal, appropriate

Results

In-Office Procedures

Urinalysis

NJU Urinalysis Auto without Micro (81003)

- GLUCOSE: Negative
- Bile, Qualitative, Urine: Negative
- Ketone: Negative
- PH: 7.5
- Urobilinogen: 0.2
- NITRATE: Negative
- Leukocytes:: Negative
- Blood: Negative
- Specific - Gravity: 1.015
- COLOR: Yellow
- APPEARANCE: Clear
- Protein: Negative

Imaging procedure

Bladder Scan (51798)

- Specimen vol Ur: 113

Assessment

- Mixed incontinence 788.33/N39.46
- Groin pain, left 789.09/R10.32
- Dyspareunia due to medical condition in female 625.0/N94.19

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Plan

Disposition

- Call or Return if symptoms worsen or persist.

Electronically Signed by: Konstantin Walmsley, MD -Author on January 16, 2017 09:57:34 PM